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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,048

Applicant(s)

EL-NAGGAR ET AL.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 8-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. By Amendment filed June 13, 2005, claims 6-7 have been cancelled; claim 1 has been amended; and claims 8-22 have been newly added. Claims 1, 5 and 8-22 are currently pending for prosecution on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 8 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Greenberg et al. (Journal of Clinical Pharmacology, 2000, 40 (12, Pt2), pp. 1509-1515).

Greenberg expressly teaches a combination of a standard therapeutic dose of rofecoxib and low dose of aspirin (81 mg aspirin) having “cardiovascular protective property”, wherein said rofecoxib and aspirin is coadministered to a patient population likely to benefit from rofecoxib anti-inflammatory therapy (i.e., osteoarthritis and rheumatoid arthritis).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 5, 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (The Journal of Clinical Pharmacology, 2000, 40 (12, Pt.2), pp. 1509-1515), and further in view of Burch et al. (US 6552031) and Drug Facts and Comparison (1995 Edition, pp. 1248).

The teaching of Greenberg has been discussed in above 35 USC 102(a) rejection.

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Burch and Drug Facts and Comparison being supplied as a reference to demonstrate the art recognized skill in preparing rofecoxib or low dose aspirin in enteric coating formulation (see column 18, line 31 thru column 23, line 3 of Burch and commercially available Bayer Low Adult Strength 81mg in Facts and Comparison). The teaching of Greenberg differs from the claimed invention in the preparation of said composition in enteric coated formulation. However, it would have been obvious to one of ordinary skill in the art to arrive at the instantly claimed enteric coated formulation for the purpose of the regulation of release or for the protection of the formulation since the preparation of rofecoxib or aspirin in enteric coatings is old and well known in the art. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

4. Claims 1, 5 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (US 6306842 B1) in view of Ares et al. (US 5399584), and further in view of Shapiro (US 6444221) and Drug Facts and Comparison (1995 Edition, pp. 1248).

Lai teaches a use of conjugates of a combination of NSAID such as aspirin and COX-2 inhibitors such as celecoxib and rofecoxib for treating inflammatory disorders (claims 2-5 and 20). Since there is no statement or indication in the instant claims that said combination must be essentially in the form of "non-covalently linked, NSAIDS and COX2 inhibitor", the referenced teaching of "covalently linked NSAIDS and COX-2 inhibitors combination" is considered relevant to the claimed invention.

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Ares teaches the use of flavonoids for treating damage to the mucosal lining of the gastrointestinal tract (e.g., gastrointestinal ulcer) caused by NSAID (abstract, column 3, lines 16-30 and lines 46-65).

Shapiro (US 6444221) teaches the use of flavonoids, flavanoids and isoflavones (i.e., daidzin, genistein, quercetin, silymarin, etc...) as antioxidants having functional equivalent property for the treatment of inflammatory disease conditions (column 9, line 52 thru column 10, line 32; column 20, line 47 thru column 21, line 8).

Shapiro is being supplied as references to demonstrate the use of flavonoids, flavanoids and isoflavones as antioxidants that are useful in the treatment of inflammatory disease conditions.

Drug Facts and Comparison being supplied as a reference to demonstrate the art recognized skill in preparing low dose aspirin in enteric coating formulation (see commercially available Bayer Low Adult Strength 81mg in Facts and Comparison).

The teaching of Lai differs from the claimed invention in i) the use of flavonoids, flavanoids or isoflavones in combination with aspirin and COX2 inhibitors and ii) use of low dose aspirin. To incorporate such teaching into the teaching of Lai, would have been obvious in view of Ares who teaches the use of flavonoids or flavones for treating damage to the mucosal lining of gastrointestinal tract caused by NSMD. One having ordinary skill in the art would have been motivated to modify the teaching of Lai such that gastrointestinal side effects associated with NSAD such as aspirin (column 1, lines 19-22 of Lai'842; column 1, lines 14-26 of ATes'584) would be greatly reduced.

With respect to the claimed low dose of aspirin (70-85mg), those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical

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practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of Drug Facts and Comparison.


Conclusion

5. No Claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to be 'Brian Kwon', with a long horizontal flourish extending to the right.